

Appl. No. 10/716,163
Amendment Dated December 28, 2004
Reply to Office action mailed July 28, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended): A pharmaceutical composition comprising:
 - a. an analgesic selected from the group consisting of morphine, meperidine, fentanyl, hydromorphone, oxymorphone, oxycodone, hydrocodone, methadone, propoxyphene, pentazocine, levorphanol and combinations thereof; and,
 - b. a stool softener selected from the group consisting of docusate, psyllium, methylcellulose, carboxymethyl cellulose, polycarbophil, and combinations thereof.
2. (Original): The pharmaceutical composition of claim 1, further comprising a non-opioid analgesic.
3. (Original): The pharmaceutical composition of claim 2, wherein the non-opioid analgesic comprises about 10 mg to about 2000 mg of acetaminophen.
4. (Original): The pharmaceutical composition of claim 2, wherein the non-opioid analgesic comprises about 325 mg to about 750 mg of acetaminophen.
5. (Cancelled)
6. (Original): The pharmaceutical composition of claim 1, wherein the stool softener comprises from about 0.1 grams to about 10.0 grams of psyllium.
7. (Original): The pharmaceutical composition of claim 1, wherein the stool softener comprises from about 0.3 grams to about 0.75 grams of psyllium.
8. (Original): The pharmaceutical composition of claim 1, wherein the stool softener comprises from about 10 mg to about 300 mg of docusate.
9. (Original): The pharmaceutical composition of claim 1, wherein the stool softener comprises from about 50 mg to about 100 mg of docusate.

10. (Original): The pharmaceutical composition of claim 1, formulated as at least one of member of the group consisting of an oral solution, oral syrup, soft gelatin capsule, hard gelatin capsule, tablet, capsule and sterile packaged powder.
11. (Original): The pharmaceutical composition of claim 1, further comprising a sustained release carrier that causes the analgesic to be released over a time period of about 4 to about 16 hours when orally administered to a human patient.
12. (Original): A pharmaceutical composition comprising:
 - a. an opioid analgesic; and,
 - b. at least about 50 mg of docusate.
13. (Original): The pharmaceutical composition of claim 12, further comprising a non-opioid analgesic.
14. (Original): The pharmaceutical composition of claim 13, wherein the non-opioid analgesic is about 10 mg to about 2000 mg of acetaminophen.
15. (Original): The pharmaceutical composition of claim 13, wherein the non-opioid analgesic is about 325 mg to about 750 mg of acetaminophen.
16. (Original): The pharmaceutical composition of claim 12, wherein the composition comprises from about 50 mg to about 300 mg of docusate.
17. (Original): The pharmaceutical composition of claim 12, further comprising one or more pharmaceutically acceptable inert excipients.
18. (Original): The pharmaceutical composition of claim 12, formulated as at least one of member of the group consisting of an oral solution, oral syrup, soft gelatin capsule, hard gelatin capsule, tablet, capsule and sterile packaged powder.
19. (Original): The pharmaceutical composition of claim 12, further comprising a sustained release carrier that causes the opioid to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.
20. (Original): The pharmaceutical composition of claim 12, wherein the opioid analgesic comprises codeine.

21. (Currently amended): A method of preventing constipation during analgesic use comprising administration of a pharmaceutical composition comprising a stool softener selected from the group consisting of docusate, methylcellulose, carboxymethyl cellulose, polycarbophil, and combinations thereof with an analgesic in a single oral dosage form, wherein said analgesic is selected from the group consisting of morphine, meperidine, fentanyl, hydromorphone, oxymorphone, oxycodone, hydrocodone, methadone, propoxyphene, pentazocine, levorphanol, ~~acetaminophen~~ and combinations thereof.
22. (Original): The method of claim 21, further comprising a non-opioid analgesic.
23. (Original): The method of claim 22, wherein the non-opioid analgesic comprises from about 10 mg to about 2000 mg of acetaminophen.
24. (Original): The method of claim 22, wherein the non-opioid analgesic comprises from about 325 mg to about 750 mg of acetaminophen.
25. (Cancelled)
26. (Original): The method of claim 21, wherein the stool softener is from about 0.1 gram to about 10.0 grams of psyllium.
27. (Currently amended): The method of claim 21, wherein the stool softener is ~~from~~ about 0.5 gram of psyllium.
28. (Original): The method of claim 21, wherein the stool softener is from about 25 mg to about 200 mg of docusate.
29. (Original): The method of claim 21, wherein the stool softener is from about 50 mg to about 100 mg of docusate.
30. (Original): The method of claim 21, wherein the single oral dosage form further comprises a sustained release carrier that causes the analgesic to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.
31. (Original): The method of claim 21, wherein the single oral dosage form is administered on an empty stomach.

32. (Original): The method of claim 21, wherein the single oral dosage form is administered with food.
33. (Original): A method of preventing constipation during analgesic use comprising administration of a stool softener with codeine in a single solid dosage form comprising:
 - a. an opioid analgesic; and,
 - b. at least about 50 mg of docusate.
34. (Original): The method of claim 33, wherein the single solid dosage form further comprises a non-opioid analgesic.
35. (Original): The method of claim 34, wherein the non-opioid analgesic is comprises about 10 mg to about 2000 mg of acetaminophen.
36. (Original): The method of claim 34, wherein the non-opioid analgesic is comprises about 325 mg to about 750 mg of acetaminophen.
37. The method of claim 33, wherein the single oral dosage form comprises from about 50 mg to about 300 mg of docusate.
38. (Original): The method of claim 33, wherein the single oral dosage form further comprises one or more pharmaceutically acceptable inert excipients.
39. (Original): The method of claim 33, wherein the single oral dosage form further comprises a sustained release carrier that causes the analgesic to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.
40. (Original): The method of claim 33, wherein the opioid analgesic is codeine.